K090532

510(k) SUMMARY

NOV 13 2009

510(k) Owner:	Vision Quest Industries, Inc. 18011 Mitchell South, Irvine, CA, 92614 Ph. (800) 266-6969 Fax (800) 821-8012
Contact:	Doug Humphrey Dir. QA and Regulatory Affairs
Date Summary Prepared:	May 22, 2009
Proprietary Name:	T.E.A.R. Tech 3
Device Type:	Interferential Stimulator High Volt Pulsed Current Stimulator Neuromuscular Electrical Stimulator
Substantial Equivalence:	This device is similar in design, composition and function to the following devices:

Manufacturer	Product Name	510(k) Number
Vision Quest Industries, Inc. 18011 Mitchell South Irvine, CA 92614	T.E.A.R. Tech3	K030507
Staodyn, Inc. 1225 Florida Avenue P. O. Box 1379 Longmont, Colorado 80502-1379	Tuwave	K921668
Compex Technologies, Inc. (formerly Staodyn) 1811 Old Highway 8 New Brighton, MN 55112	IF3 Wave	K050046

Device Description:

The T.E.A.R. Tech 3 IF/Muscle Stimulator is a device which combines the functionality of Interferential (IF), Neuromuscular (NM), High Voltage (HV) and Pulsed Direct Current (PDC) in one device. The device produces a low electrical current that is

transmitted via lead wires to electrodes placed on the skin in the area predetermined by a clinician. Operating parameters can be adjusted throughout their range by a trained clinician but the end-user is limited to protocol selection and amplitude. The user interface consists of an LCD display and keypad.

Indications for Use:

The T.E.A.R. Tech3 IF/Muscle Stimulator is intended for the following applications:

The High Volt Pulsed Current Stimulation and Neuromuscular Electrical Stimulation can be used in the following applications:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increases local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Interferential Stimulation can be used in the following applications:

- Symptomatic relief of post traumatic acute pain
- Symptomatic relief of chronic pain intractable pain
- Relaxation of muscle spasms
- Maintaining or increasing range of motion
- Increases local blood circulation

Pulsed Direct Current stimulation can be used in the following applications:

- Reduction of edema (under negative electrode)
- Relaxation of muscle spasm
- Increasing local blood circulation
- Retardation or prevention of disuse atrophy
- Muscle re-education
- Maintaining or increasing of range of motion

The target population for this device is patients with chronic, acute pain syndrome, and/or recovering from orthopedic related surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Vision Quest Industries, Inc.
% Mr. Wallace Fischer
18011 Mitchell South
Irvine, California 92614

NOV 13 2009

Re: K090532
Trade/Device Name: T.E.A.R. Tech3
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, LIH
Dated: October 13, 2009
Received: October 16, 2009

Dear Mr. Fischer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

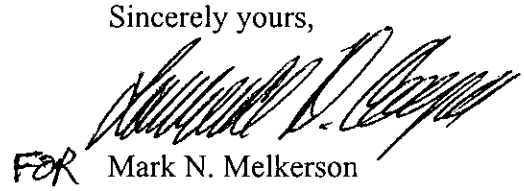
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090532

Device Name: T.E.A.R. Tech3

Indications For Use:

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- Symptomatic relief of post traumatic acute pain
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- Maintaining or increasing range of motion
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- Reduction of edema (under negative electrode)
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- Increasing local blood circulation
- Retardation or prevention of disuse atrophy
- Muscle re-education
- Maintaining or increasing of range of motion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. NELSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090532